HAEMONETICS®
THE Blood Management Company

510(k) Summary .

Date: June 26, 2015

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Device Information:

Trade Name:	Haemonetics MCS+ 8150 Apheresis System
Common Name:	Automated Blood Cell Separator
Classification Name:	Separator, Automated, Blood Cell, Diagnostic
Regulation Number:	21 CFR 864.9245
Device Class:	Class II
Product Code:	GKT

Legally Marketed Predicate Device:
Haemonetics MCS+ 8150 Apheresis system (BK140108)

Trade Name:	Haemonetics MCS+ 8150 Apheresis System
Common Name:	Automated Blood Cell Separator
Classification Name:	Separator, Automated, Blood Cell
Regulation Number:	21 CFR 864.9245
Device Class:	Class II
Product Code:	GKT

Device Characteristics Summary:
The subject of this Special 510(k) is the Haemonetics MCS+ 8150 System North American (NA) Software Revision L.3 and related hardware components that together offer bidirectional wired or wireless connectivity between the MCS+ 8150 device and an approved server application.

The MCS+8150 is an automated blood cell separator. The device and associated disposables have been cleared via numerous premarket notifications for various indications for use. The MCS+ 8150 multicomponent collection system is dedicated to red blood cell collection procedures (with plasma as a byproduct), and is based upon automated Apheresis technology. The device is a combination of two subsystems: an electro-mechanical device and a disposable set. The two subsystems are integrated to perform the component collection function.

The device is designed to increase donor management capability, helping to use fewer donors to achieve collection needs, and offering versatility with multiple protocols to meet collection goals. The MCS+ 8150 system is compact, lightweight, and mobile.

Indications for Use:
The MCS+ 8150 device may be used to collect the following blood components from allogeneic and autologous donors.

- Two units of Red Blood Cells collected and stored in CP2D/AS-3. (832 disposable set) *Two Unit Red Blood Cell Protocol.*
- One unit of Red Blood Cells collected and stored in CP2D/AS-3 and one unit of plasma. (822 and 822-2P disposable sets) *Red Blood Cells and Plasma Protocol.*
- Two units of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3. (832F disposable set) *Two Unit Red Blood Cell Protocol* Filtration must be done within 8 hours of phlebotomy if the Red Blood Cells are at room temperature or within 72 hours of phlebotomy if the Red Blood Cells are stored at 1-6°C.
- One unit of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3, and plasma. (822F-2P disposable set) *Filtered Red Blood Cell and Plasma Protocol.*

  Filtration must be between 6-72 hours post phlebotomy on cells that have been stored at 1-6°C.

Plasma collected using the 822, 822-2P, and 822F-2P disposable sets may be:
- Fresh Frozen Plasma
    - *Must be prepared and placed in a freezer at -18°C or colder within 8 hours of phlebotomy.*

- Source plasma
- Plasma frozen within 24 hours after phlebotomy (PF24)
    - *Must be stored at 1-6°C within 8 hours of phlebotomy and placed in a freezer at -18°C or colder within 24 hours after phlebotomy.*
    - *Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.*

One unit of CP2D/AS-3 Red Blood Cells may be collected from allogeneic donors in the event of a terminated procedure after the first draw cycle ends. (832 & 832F disposable set).

Non-Clinical Testing Summary:
The following non-clinical performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the performance testing is presented below in Table 1. Test data demonstrates that the device met all performance requirements, and that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Table 1: Summary of Performance Studies

Test Name	Summary Report #	Test Intent	Test Result
Electromagnetic Compatibility	TR-ELE-100751	To verify compliance with EMC requirements per IEC 60601-1-2.	Passed
Electrical Safety	TR-ELE-100752	To verify compliance with electrical safety requirements per IEC 60601-1.	Passed
Wireless Coexistence	TR-ELE-100753	To verify wireless coexistence of the MCS+ 8150 with potential interference appliances.	Passed
Software Validation	TR-SOF-100549 TR-SOF-100549-A	To validate revision L.3 of the MCS+ 8150 NA software.	Passed

Comparison to Predicate:

The Haemonetics MCS+ 8150 System with North American (NA) Software Revision L.3 for bidirectional connectivity is substantially equivalent to the MCS+ 8150 System North American (NA) Software Revision L.1, cleared under BK140108. The MCS+ 8150 NA Software Revision L.3 is intended for use with the same hardware and disposables as the predicate device, and in the same operating environment with the same donor/operator population. The indications for use are the same. The technological characteristics of the subject device differ from the predicate only in the rear panel hardware and the software revision. These differences do not render the device non-substantially equivalent because non-clinical testing has demonstrated that the subject device is as safe and effective as the predicate and the results of verification and validation have not raised different questions of safety and effectiveness than the predicate.

Table 2 compares the indications for use hardware, disposable and software used of the predicate MCS+ 8150 with NA software L. 1 (BK140108) and the proposed device with MCS+ 8150 with NA software L.3. In conclusion the differences do not constitute a new intended use or did not raise any different questions of safety or effectiveness and therefore did not render the device not substantially equivalent.

A summary comparison is presented below in Table 2.

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Table 2: Comparison of the MCS+ 8150 NA Software Revision L.3 for Bidirectional Connectivity to the Predicate MCS+ 8150 NA Software Revision L and higher

	Predicate **NA Software Rev L.1 (BK140108)**	**Subject** **MCS+ 8150 NA Software Revision L.3 for Bidirectional Connectivity**
Manufacturer	Haemonetics Corporation	Same
Trade Name	Haemonetics MCS+ 8150 Apheresis System	Same
Common Name	Automated Blood Cell Separator	Same
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same
Regulation Number	21 CFR 864.9245	Same
Product Code	GKT	Same
Device Class	II	Same
Indications for Use	The MCS+ 8150 device may be used to collect the following blood components from allogeneic and autologous donors. • Two units of Red Blood Cells collected and stored in CP2D/AS-3. (832 disposable set) *Two Unit Red Blood Cell Protocol* • One unit of Red Blood Cells collected and stored in CP2D/AS-3 and one unit of plasma. (822 and 822-2P disposable sets) *Red Blood Cells and Plasma Protocol* • Two units of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3. (832F disposable set) *Two Unit Red Blood Cell Protocol* Filtration must be done within 8 hours of phlebotomy if the Red Blood Cells are at room temperature or within 72 hours of	Same (with addition of 832 Series per FDA's request) The MCS+ 8150 device may be used to collect the following blood components from allogeneic and autologous donors. • Two units of Red Blood Cells collected and stored in CP2D/AS-3. (832 disposable set) *Two Unit Red Blood Cell Protocol* • One unit of Red Blood Cells collected and stored in CP2D/AS-3 and one unit of plasma. (822 and 822-2P disposable sets) *Red Blood Cells and Plasma Protocol* • Two units of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3. (832F disposable set) *Two Unit Red Blood Cell Protocol* Filtration must be done within 8 hours of

	Predicate NA Software Rev L.1 (BK140108)	Subject MCS+ 8150 NA Software Revision L.3 for Bidirectional Connectivity

	phlebotomy if the Red Blood Cells are stored at 1-6°C.
	• One unit of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3, and plasma. (822F-2P disposable set) *Filtered Red Blood Cell and Plasma Protocol.* Filtration must be between 6-72 hours post phlebotomy on cells that have been stored at 1-6°C.
	
	Plasma collected using the 822, 822-2P, and 822F-2P disposable sets may be:
	• Fresh Frozen Plasma
	  • *Must be prepared and placed in a freezer at -18°C or colder within 8 hours of phlebotomy.*
	• Source plasma
	• Plasma frozen within 24 hours after phlebotomy (PF24)
	  • *Must be stored at 1-6°C within 8 hours of phlebotomy and placed in a freezer at -18°C or colder within 24 hours after phlebotomy.*
	  • *Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma*
		phlebotomy if the Red Blood Cells are at room temperature or within 72 hours of phlebotomy if the Red Blood Cells are stored at 1-6°C.
		• One unit of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3, and plasma. (822F-2P disposable set) *Filtered Red Blood Cell and Plasma Protocol.* Filtration must be between 6-72 hours post phlebotomy on cells that have been stored at 1-6°C.
		
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		One unit of CP2D/AS-3 Red Blood Cells may be collected

	Predicate NA Software Rev L.1 (BK140108)	Subject MCS+ 8150 NA Software Revision L.3 for Bidirectional Connectivity
	One unit of CP2D/AS-3 Red Blood Cells may be collected from allogeneic donors in the event of a terminated procedure after the first draw cycle ends. (832 disposable set)	from allogeneic donors in the event of a terminated procedure after the first draw cycle ends. (832 & 832F disposable set)
Hardware	Automated apheresis device incorporating centrifuge, pumps, optical sensors, pressure monitors, and membrane panel which, together with single-use disposable sets and embedded software, separates blood and collects plasma, returning remaining blood components to the donor.	NA Software Revision L.3 for bidirectional connectivity operates on existing MCS+ 8150 hardware via installation of the new software and replacement of the existing rear panel of the device with an equivalent rear panel modified to accommodate a wireless module carrier PCB assembly, including a connector to be used for wired network connectivity and a connector to interface with a 2D barcode scanner. **The principal of operation remain the same:** Automated apheresis device incorporating centrifuge, pumps, optical sensors, pressure monitors, and membrane panel which, together with single-use disposable sets and embedded software, separates blood and collects plasma, returning remaining blood components to the donor.
Disposables	There were no changes to the MCS+ 8150 System disposables associated with the changes that are the subject of this 510(k) application.	

	Predicate NA Software Rev L.1 (BK140108)	Subject MCS+ 8150 NA Software Revision L.3 for Bidirectional Connectivity
Software	NA Software Revision L.1	NA Software Revision L.3, same technology with bidirectional connectivity

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